

and "the Interferin method is positively superior to dilation and curettage in cases of gravidity from two and a half to six months," were false and misleading since, in cases of abortion induced by the use of the article, the placenta would not usually be expelled a few minutes after the fetus, severe hemorrhages would not be rarely observed after the use of the article, but would frequently occur after such use, and the results obtained by the use of the article in cases of gravidity from 2½ to 6 months would not be superior to those obtained by dilation and curettage.

Misbranding (shipment of March 19, 1942), Section 502 (a), the labeling statements, "Caution: For use by Licensed Physician only. * * * Indications Amenorrhea, Dysmenorrhea, Endocervicitis, Endometritis, Spontaneous, Incomplete, Threatened Abortion," were false and misleading since they represented and suggested that the article, when used by a licensed physician, was a safe and appropriate medicament for use in the treatment of spontaneous, incomplete, and threatened abortion, and that it was a safe and appropriate treatment for amenorrhea, dysmenorrhea, endocervicitis, and endometritis. The article, whether used by a licensed physician or otherwise, was not a safe and appropriate medicament for the treatment of such conditions, but was unsafe and dangerous, and capable of producing serious and even fatal consequences.

DISPOSITION: June 21, 1945. A plea of nolo contendere having been entered by the defendant, the court imposed a sentence of 1 year in jail, to run concurrently with the sentence imposed in the case reported in notices of judgment on drugs and devices, No. 1558.

1553. Misbranding of Stanley's Stomach Powder, Prescription 1-NN-1 Nerve Tablets, Prescription 1-RR-7, External No. 1, Prescription 1-H-7, and Prescription Medicine 1-B-7. U. S. v. Sophia Strboya Sikoparija (Stanley's Drug Store). Plea of not guilty. Tried to the jury; verdict of guilty. Sentence of 57 days in jail. (F. D. C. No. 11379. Sample Nos. 14838-F, 14839-F, 15010-F, 15011-F, 38339-F, 38340-F.)

INFORMATION FILED: May 8, 1944, Eastern District of Texas, against Sophia Strboya Sikoparija, trading as Stanley's Drug Store, Orange, Tex.

ALLEGED SHIPMENT: Between the approximate dates of January 21 and February 20, 1943, from the State of Texas into the States of Wisconsin and California.

PRODUCT: Analyses disclosed that the *Stanley's Stomach Powder* consisted essentially of sodium bicarbonate and Rochelle salt, flavored with anise oil; that the *Prescription 1-NN-1 Nerve Tablets*, the *Prescription 1-RR-7*, and the *Prescription Medicine 1-B-7* contained ½ grain of phenobarbital per tablet; that the *External No. 1* consisted essentially of basic aluminum acetate and sodium acetate; and that the *Prescription 1-H-7* consisted essentially of extracts of plant drugs, including a laxative drug such as senna, sugar, alcohol, and water.

NATURE OF CHARGE: *Stomach Powder*, misbranding, Section 502 (a), certain label statements were false and misleading since they represented and suggested that the article would be beneficial in the treatment of stomach disorders; that it would be efficacious in the cure, mitigation, treatment, or prevention of stomach pain due to gas, nausea, and heaviness after meals; and that it would be efficacious to correct indigestion, strengthen the digestive organs, and soothe and heal stomach tissues, whereas it would not be efficacious for such purposes; Section 502 (b) (2), the label bore no statement of the quantity of the contents; and, Section 502 (e) (2), the label did not bear the common or usual names of the active ingredients of the article.

Prescription 1-NN-1 Nerve Tablets, misbranding, Section 502 (a), certain label statements were false and misleading since they represented and suggested that the article would be efficacious in the cure, mitigation, treatment, and prevention of nervousness, restlessness, sleeplessness, worry or excitement, depressed spirits, and nervous headaches, whereas the article would not be efficacious for such purposes; Section 502 (d), the article contained phenobarbital, a derivative of the narcotic or hypnotic substance barbituric acid, which derivative has been found to be and by regulations designated as habit forming, and its label failed to bear the name and quantity or proportion of such derivative and, in juxtaposition therewith, the statement "Warning—May be habit forming"; Section 502 (j), the article consisted of tablets, each containing approximately ½ grain of phenobarbital, and it would be dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in its labeling, "Direction: Adults: Take 1 Tablet three times a

day with full glass of water"; and, Section 502 (b) (2), the label of the article bore no statement of the quantity of the contents.

Prescription 1-RR-7, misbranding, Section 502 (a), certain statements on the label were false and misleading since they represented and suggested that the article would be efficacious in the cure, mitigation, treatment, and prevention of high blood pressure, headaches, heat and fullness of the head, heat and redness of the face, dizziness, noise in the ears, sleeplessness at night, and oppressed breathing due to rush of blood to the head, whereas the article would not be efficacious for such purposes; Section 502 (d), the article contained phenobarbital and its label failed to bear the required warning; Section 502 (b) (2), the label of the article bore no statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the article bore no directions for use.

External No. 1, misbranding, Section 502 (a), the label statement, "cover the sore," was false and misleading since it represented and suggested that the article would be efficacious in the cure, mitigation, or treatment of sores, whereas it would not be efficacious for such purposes; Section 502 (b) (2), the label of the article bore no statement of the quantity of the contents; and, Section 502 (e) (2), the label of the article failed to bear the common or usual name of each active ingredient of the article.

Prescription 1-H-7, misbranding, Section 502 (a), certain label statements were false and misleading since they represented and suggested that the article would be efficacious in the treatment of liver ailments; that it would be efficacious in the cure, mitigation, treatment, or prevention of disordered conditions of the liver, stomach, and bowels; and that it would have a tonic effect upon the large intestine, whereas the article would not be efficacious for such purposes; Section 502 (e) (2), the label failed to bear the common or usual names of the active ingredients of the article; and, Section 502 (f) (2), the article was a laxative and its label failed to warn that it should not be taken when abdominal pain, nausea, vomiting, or other symptoms of appendicitis were present, and its labeling also failed to warn that frequent or continued use of the article might result in dependence upon a laxative to move the bowels.

Prescription Medicine 1-B-7, misbranding, Section 502 (a), certain label statements were false and misleading since they represented and suggested that the article would be efficacious in the cure, mitigation, treatment, or prevention of nervousness, sleeplessness, worry, and weak nerves, whereas it would not be efficacious for such purposes; Section 502 (d), the article contained phenobarbital and its label failed to bear the required warning; Section 502 (j), the article would be dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in its labeling, (translation from Slovenian) "Directions: 1 portion 3 times a day before meals with half a cup of lukewarm water. Later it suffices to use 1 or 2 a day"; and, Section 502 (c), adequate directions for use required by Section 502 (f) (1) did not appear on the label in such terms as to render them likely to be read and understood by the ordinary individual under customary conditions of purchase or use, since that information was not in the English language.

The information also alleged that another article, *Hair Milk*, was misbranded under the provisions of the law applicable to cosmetics, as reported in notices of judgment on cosmetics.

DISPOSITION: A plea of not guilty having been entered on behalf of the defendant the case came on for trial before a jury on October 24, 1944. The jury returned a verdict of guilty, and on October 25, 1944, the court sentenced the defendant to serve 57 days in jail.

1554. Misbranding of Dimels Capsules and Aditis Capsules. U. S. v. Jones-Hague, Inc., and Carlos W. Jones. Pleas of not guilty. Tried to the court and jury; verdict of guilty. Motion for new trial denied. Fine, \$100 and costs. (F. D. C. No. 10590. Sample Nos. 2557-F, 3345-F, 3809-F.)

INFORMATION FILED: December 31, 1943, Western District of Pennsylvania, against Jones-Hague, Inc., a corporation, and Carlos W. Jones, president and treasurer, McKeesport, Pa.

ALLEGED SHIPMENT: On or about July 15, 1942, and March 11 and April 8, 1943, from the State of Pennsylvania into the State of Missouri.

LABEL, IN PART: "Dimels * * * Contains Hormone Complexes as found in Isles Langerhans," and "Aditis * * * Contains Strychnine Sulphate. 1/200 gr. * * * Thyroid Glands U. S. P. 1 Gr. * * * Barium Iodide 1/10 gr. Leptandrin 1/8 gr. Vehicle q. s."